

## FDA checking fever-related seizures in children after flu shot

January 20, 2011

**MIKE STOBBE**

ASSOCIATED PRESS

ATLANTA—U.S. government officials are investigating an apparent increase in fever-related seizures in young children after they got a flu shot.

The U.S. Food and Drug Administration on Thursday said there have been 36 confirmed reports of seizures this flu season in children ages 6 months through 2 years. The seizures occurred within one day after they were vaccinated with Fluzone, the only flu shot recommended in the United States for infants and very young children. Ten of the children were hospitalized, but all recovered.

It is not clear if the same vaccine has been distributed in Canada.

The FDA said it is investigating to see if there is any connection between the vaccine and the seizures, or if something else caused the convulsions. The agency said recommendations for using the vaccine have not changed, nor has there been any change in flu vaccine guidance.

In the U.S., vaccination is recommended for everyone except infants under 6 months.

The vaccine's manufacturer, Sanofi Pasteur, issued a statement emphasizing that no clear link has been established between the flu shot and the seizures and that the cases may be coincidental.

Thursday's announcement comes at a time when the FDA has been working on disclosing more information about potential safety problems with drugs and devices after they've been approved.

The government uses a national reporting system to monitor possible side effects following vaccination. Doctors, nurses, parents and vaccine manufacturers all can file reports.

"It's meant to cast a wide net" to look for problems, but is only regarded as preliminary information that must be checked out, said Shelly Burgess, an FDA spokeswoman.

FDA officials said they've been paying special attention to seizure reports because of an unexplained higher rate of fevers and seizures in young children in Australia and New Zealand who got a specific flu vaccine earlier this year.

In August, a U.S. vaccines advisory panel said doctors should avoid using that vaccine, made by CSL Biotherapies, in children ages 6 months through 8 years.

It's possible the Australia cases sparked increased reports this fall, said Dr. Andrea Sutherland, an official in the FDA's Center for Biologics Evaluation and Research.

The fever-related seizures — called febrile seizures — are convulsions brought on by a fever in infants or small children. A child often loses consciousness and shakes. Most seizures last a minute or two, and often children quickly recover.

Such seizures may occur with any common childhood illnesses that may cause fever, such as ear infections, colds, influenza and other viral infections.

EDITOR'S PICKS